

REMARKS

Claims 1-20 are pending. Claims 1-20 stand rejected.

Claims 1 and 12 have been amended to state that the active ingredient is solubilized or dispersed in an aqueous environment. Support for this amendment is found at p. 7, lines 5-6 of the Specification. Accordingly, no new matter is introduced by these amendments.

Reply to the Rejection of Claims 7-10, 14 and 15 under 35 U.S.C. § 112, 2nd paragraph

Claims 7-10, 14 and 15 stand rejected under 35 U.S.C. § 112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in that the phrase “at least about” allegedly does not define specific range limitations, rendering the claims indefinite. For the following reasons, Applicants respectfully traverse the Examiner’s rejection of claims 7-10, 14 and 15 under 35 U.S.C. § 112, 2nd paragraph.

Regarding the term ‘about’, use of such term as recited in claims 7-10, 14 and 15 is permissible patent claiming practice (*see*, MPEP 2173.05(b)). Claims 7-10 and 14 define the lower limit (minimum amount) of the claimed ingredient. One skilled in the art would understand the upper limit to be up to 100%. Claim 15 defines both a lower and upper limit. Accordingly, claims 7-10, 14 and 15 are not indefinite.

It is believed that these remarks overcome the Examiner’s rejection of claims 7-10, 14 and 15 under 35 U.S.C. § 112, 2nd paragraph. Withdrawal, therefore, of this rejection is respectfully requested.

Reply to the Rejection of Claims 1-6 and 16-20 under 35 U.S.C. §§ 102(b)

The Examiner has rejected claims 1-6 and 16-20 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,599,554 to Majeti (“Majeti”). For the following reasons, Applicants respectfully traverse the Examiner’s rejection of claims 1-6 and 16-20 under 35 U.S.C. § 102(b).

Majeti teaches a transdermally or transmucosally administrable composition containing nicotine and caffeine or caffeine equivalent for the treatment of nicotine craving or smoking withdrawal symptoms (Abstract). The active ingredient carrier of Majeti includes transdermal or buccal patches, bioadhesive and mucoadhesive films, as well as formulations for delivering the nicotine and caffeine in a sustained release system or at varying intervals or levels throughout the transdermal or transmucosal administration of the composition (col. 3, lines 37-48).

Accordingly, Majeti is directed towards nicotine/caffeine patches for a sustained delivery of the active. In contrast, the presently claimed invention is directed towards films that are dissolvable. It is well established that in order for a reference to anticipate a claim, that single reference must teach each and every element as set forth in the claim. As Majeti does not teach or suggest dissolvable films, Majeti cannot be said to anticipate the presently claimed invention.

For at least these reasons Majeti does not anticipate claims 1-6 and 16-20 of the present invention. Withdrawal, therefore, of the rejection of claims 1-6 and 16-20 as being anticipated by Majeti is respectfully requested.

Reply to the Rejection of Claims 7-9, 14 and 15 under 35 U.S.C. §§ 103(a)

The Examiner has rejected claims 7-9, 14 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Majeti. For the following reasons, Applicants respectfully traverse the Examiner's rejection of claims 7-9, 14 and 15 under 35 U.S.C. § 103(a).

The teachings of Majeti have been discussed above. As noted above, Majeti does not teach or suggest dissolvable films. Claims 7-9, 14 and 15 are directed towards specific percentages or amounts of caffeine in the dissolvable films of the present invention, which is not disclosed by Majeti. Accordingly, for at least those reasons previously stated, Majeti does not render obvious dissolvable films for rapid release of actives and therefore does not render claims 7-9, 14 and 15 unpatentable. Withdrawal, therefore, of the rejection of claims 7-9, 14 and 15 as being unpatentable over Majeti is respectfully requested.

Reply to the Rejection of Claims 1-5, 10-13 and 16-19 under 35 U.S.C. §§ 103(a)

The Examiner has rejected claims 1-5, 10-13 and 16-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2005/0013847 to Ballard ("Ballard"). For the following reasons, Applicants respectfully traverse the Examiner's rejection of claims 1-5, 10-13 and 16-19 under 35 U.S.C. § 103(a).

Ballard discloses a homogenous, thermoreversible gel film, wherein the gel film comprises a film forming amount of a water soluble thermoreversible alginate, and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent; and an active substance ([¶¶ 0002], [0006]). According to the process of Ballard, a dry premix of the alginate and other ingredients are added to a water/glycerin mixture, heated and agitated for a time sufficient to fully hydrate the gums. The active is then added to the mixture and dispersed ([¶¶ 0100]).

Claims 1 and 12 have been amended to state that the active ingredient is solubilized or dispersed in an aqueous environment, and then the film formers are added. Accordingly, the films of Ballard are made according to a process different from that of the presently claimed invention. With respect to claim 3 of the present application, Ballard only teaches a dispersion of its active ingredient. It is believed that, due to the process and ingredients utilized by Ballard, a solution cannot be formed.

For at least these reasons Ballard does not render obvious claims 1-5, 10-13 and 16-19 of the present invention. Withdrawal, therefore, of the rejection of claims 1-5, 10-13 and 16-19 as being unpatentable over Ballard is respectfully requested.

Reply to the Rejection of Claims 6-9, 14, 15 and 20 under 35 U.S.C. §§ 103(a)

The Examiner has rejected claims 6-9, 14, 15 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Ballard in view of Majeti. For the following reasons, Applicants respectfully traverse the Examiner's rejection of claims 6-9, 14, 15 and 20 under 35 U.S.C. § 103(a).

Ballard and Majeti have been previously discussed. It is believed that the Examiner combines the teachings of Majeti with Ballard due to the belief that Ballard does not specifically teach the active ingredient caffeine. Applicants respectfully direct

the Examiner's attention to paragraph [0100] (Example 5) of Ballard, wherein the third active ingredient added to the film of Ballard is caffeine.


Still, as previously noted, Majeti does not teach dissolvable films. Ballard does not teach or suggest first solubilizing or dispersing the active ingredient in an aqueous environment, and then adding the film formers to form a mixture. With respect to the process utilized in forming the films of Majeti, Majeti simply states that "[t]he above ingredients are prepared to methods known in the art" (*see*, Examples I and II of Majeti). Accordingly, one skilled in the art would not know from the teachings of Ballard and Majeti to first solubilize or disperse an active ingredient in an aqueous environment, and then add film formers to form a mixture in order to form a film that provides a rapid release of its active ingredient.

For at least these reasons Ballard in view of Majeti does not render obvious claims 6-9, 14, 15 and 20 of the present invention. Withdrawal, therefore, of the rejection of claims 6-9, 14, 15 and 20 as being unpatentable over Ballard in view of Majeti is respectfully requested.

Based on the above amendments and remarks, it is believed that the present application is in form for allowance, and such allowance is respectfully requested.

Respectfully submitted,

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